

REMARKS

Applicants respectfully request consideration of the subject application. This Response is submitted in response to the Office Action mailed December 18, 2007. Claims 1, 2, 4 and 17 are pending. In this Amendment, claims 1 and 17 have been amended, claims 13, 14, 15, and 16 have been cancelled and substantially incorporated into claim 1. No new matter has been added.

35 U.S.C. § 103 Rejections

Claims 1, 2, 4, and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Chin, et al.** (JP 07-089863 A, hereinafter "Chin"); in view of **Ishida, et al.** (JP 63-216432 A, hereinafter "Ishida") in view of **Tsuji, et al.** (JP 2001-112437 A, hereinafter "Tsuji"); in view of **Shibata** ("Chemistry and Cancer Preventing Activities of Ginseng Saponins and Some Related Triterpenoid; in further view of **Bae, et al** ("Metabolism of 20(S)-and 20 (R)-Ginsenoside R_{g3} by Human Intestinal Bacteria and Its Relation to *in Vitro* Biological Activities", Biological and Pharmaceutical Bulletin, Vol. 25, No. 1, pages 58-63, 2002, hereinafter "Bae"); in further view of **Roberfroid** ("Prebiotics and probiotics: are they functional foods?", The American Journal of Clinical Nutrition, 2000; 71(suppl):1682S-7S, hereinafter "Roberfroid"); **Hikino, et al.** (JP 61-115013 A, hereinafter "Hikino"); **Hashimoto, et al.** (JP 03-277247 A, hereinafter "Hashimoto"); and in further view of http://web.archive.org/web/*/<http://->

www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm (hereinafter "diabetic-lifestyle").

Claim 1 requires:

1. *A method of preparing a pharmaceutical composition comprising:*
treating ginseng (Panax ginseng or Panax quinquefolius) with an acid solution selected from the group consisting of acetic acid, citric acid, lactic acid, and acid from acid-containing food;
extracting an organic extract from the ginseng by utilizing an organic solvent;
subsequently fermenting the organic extract with a lactic-acid bacteria;
subsequently isolating a pharmacologically active fraction or saponin compound from the organic extract; and
subsequently drying the organic extract by lyophilization or spray drying.

(Emphasis added).

The Examiner cites specific pages of Chin (as the primary reference) which is a Japanese publication; however, no translation copy has been provided by the Examiner. As best understood from the Japanese machine translation of Chin, Chin only shows a method for isolating or purifying ginsenoside-Re.

There is no mention in Chin of a pharmaceutical composition or acid solution in Chin as recognized by the Examiner. Furthermore, Chin does not describe adding an acid solution consisting of acetic acid, citric acid, lactic acid, and acid from acid-containing food and then subsequently fermenting the organic extract and isolating a pharmacologically active fraction or saponin

compound as required by the claim. Chin also does not show subsequently drying the organic extract by lyophilization or spray drying as required by the claims.

The Examiner further relies upon Ishida to show a medicinal ginseng in a yogurt. However, Ishida also does not show treating ginseng with a specific acid solution in addition to the other limitations of the claims. Thus, Ishida does not show each and every limitation.

The Examiner further relies upon Tsuji to show adding acid to a composition of different bacteria. As best understood from the Japanese machine translation of Tsuji, an acid is added to fermented milk to improve the survival ratio of certain bacteria. Tsuji is completely unrelated to treating ginseng with an acid solution and does not show the specific acid solution or process steps required in the claims. Tsuji states in the abstract:

"PROBLEM TO BE SOLVED: To provide a process for the economical production of a food or drink such as fermented milk and yogurt containing bacteria of the genus Bifidobacterium and having high survival ratio of the bacteria in the product."

As noted above, Tsuji is specific to a problem unrelated to ginseng extract and does not show each and every element of the claims.

The Examiner further relies upon Shibata to show lactic acid bacterial. Shibata is related to the cancer preventing activities of ginseng and saponins and

general discusses human intestinal microflora, which metabolize ginsenoside Rb-1 and Rb-2 to compound K.

Again, Shibata does not show adding a specific acid to ginseng and then processing an extract in the specific order of steps as required by the claims.

As relied upon by the Examiner, Bae and Roberfroid discuss various characteristics of lactobacilli and bifidobacteria but do not show each and every element of the claims as amended.

Applicant respectfully requests clarification of the Examiner's rejection. The Examiner has cited the Morishita reference but has not included the Morishita reference in the statement of rejection. Applicant respectfully requests clarification of whether the Morishita reference is being relied upon by the Examiner.

Furthermore, it is unclear to the Applicant how the Hashimoto et al. reference is applied in the rejection because Hashimoto et al. is not applied in the main body of the rejection.

The Hikino reference is related to a cosmetic containing a polysaccharide existing in ginseng as applied to beauty and health concerns. Hikino also fails to show treating ginseng with a specific acid solution and the method steps required in the claims. The website cited by the examiner also does not show each and every limitation of the claim.

The Examiner cites MPEP §2112.01 with respect to the product by process claim. However, Applicant respectfully draws the attention of the Examiner to the cited section of the MPEP §2112.01 which is entitled:

"2112.01 Composition, Product, and Apparatus Claims[R-3]
I. PRODUCT AND APPARATUS CLAIMS WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT"(Emphasis added).

As clearly shown by the title, the section the examiner has relied upon is only applicable to product and apparatus claims. The Examiner also contends that the order of method steps do not matter and cites MPEP §2111.01(I). However, MPEP §2111.01(I) is related to the Plain Meaning interpretation of claims and does not state that the order of method steps can be ignored.

The current pending claims are method claims and cannot be construed as product-by-process claims. Furthermore, the method of the present invention is not shown in the prior art as discussed above.

The serial treatment of ginseng as claimed in claim 1 shows substantial enhanced pharmacological effects, especially in the area of brain stroke prevention as described in paragraphs [0080]-[0086] and Figure 1 of the specification.

Thus, the cited art fails to teach or suggest all of the limitations of independent claim 1. Claims 2, 4 and 17 depend, directly or indirectly, from claim 1. Applicants, accordingly, respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

Applicants respectfully submit that the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite or assist in the allowance of the present application, the Examiner is invited to call the undersigned at (408) 720-8300.

Please charge any shortages and credit any overages to Deposit Account No. 02-2666. Any necessary extension of time for response not already requested is hereby requested. Please charge any corresponding fee to Deposit Account No. 02-2666.

Respectfully submitted,
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Date: April 2, 2008



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